Northern Ireland Assembly

Windsor Framework Democratic Scrutiny Committee

OFFICIAL REPORT (Hansard)

Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC and 2004/23/EC

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Members present for all or part of the proceedings:
Mr Philip McGuigan (Chairperson)
Mr David Brooks (Deputy Chairperson)
Dr Steve Aiken
Ms Joanne Bunting
Ms Connie Egan
Mr Declan Kearney

Witnesses:

Ms Brenda McGilligan	Department of Health
Mr Ryan Wilson	Department of Health

The Chairperson (Mr McGuigan): I welcome Ryan Wilson, director of secondary care in the Department of Health, and Brenda McGilligan, head of EU future relations branch in the Department of Health. I will hand over to you to brief the Committee on the regulation.

Mr Ryan Wilson (Department of Health): Thank you, Chair, and good morning, members. Thank you for the opportunity to provide the Committee with some background information on regulation (EU) 2024/1938 on substances of human origin (SoHO). The legislation repeals and replaces directives 2002/98/EC and 2004/23/EC on blood tissues and cells, which apply to Northern Ireland under the Windsor framework, and brings a number of additional substances into scope.

The published replacement (PUBR) assessment template, which Committee members have received, contains more detail on the regulation and on the relevant services to which it will apply. We have today received a copy of the UK Government's explanatory memorandum (EM). I understand that members have also received that today, and you may wish to consider that in full. Our objective today is to provide the Committee with an overview of the details of the SoHO regulation based on the Department's understanding, at this stage.

I want to set out for you the purpose of the SoHO regulation and the changes that it introduces that will apply to Northern Ireland and departmental officials' current understanding of the UK Government's position in respect of SoHO. I will highlight that, whilst the legislation will not come into force until 2027, there is extensive work to be undertaken by the European Commission, member states and the UK Government to establish the appropriate structures and mechanisms. The Department of Health and Social Care (DHSC) in England has been actively leading in this policy area on behalf of the UK Government and will continue to do so. I will return to the UK Government position shortly.

First, I will cover the purpose and scope of the regulation. It aims to raise the minimum safety and quality standards of SoHO materials that are intended for human application and for activities related to those substances. They are substances collected from the human body, including SoHO preparations resulting from the processing of those substances. While our Department welcomes any measures to further enhance standards in this area, especially given the growth in the clinical application of SoHO to save and improve patients' lives, it is important to note that the UK already has very high standards in quality and safety. That is what underpins the movement of SoHO to and from Northern Ireland, enabling those services to be provided to our patients. Our Department's primary objective is, therefore, to ensure continued access to the substances and to avoid any potential for disruption to clinical services.

The regulation applies to SoHO intended for human application; SoHO donors and recipients and the offspring from medically assisted reproduction; and SoHO activities that have a direct impact on the quality, safety and effectiveness of SoHO. Whilst the existing blood, tissues and cells directives set out a range of quality and safety standards and requirements, this SoHO regulation addresses gaps that have occurred as a result of the scientific, technical and medical advances in transfusion and transplantation.

Since donation and human application of SoHO other than those regulated by the existing blood, tissues and cells directives are increasingly common, it was necessary to extend the scope of the regulation to ensure the protection of all SoHO donors and recipients. Therefore, SoHO now extends to human breast milk, intestinal microbiota, blood preparations that are not used in transfusion and, potentially, other SoHO that might be applied to humans in future.

It is important to note that the regulation does not apply to solid organs intended for transplantation. Thus, there is no impact on the organ donation and transplantation system. The regulation does not apply to breast milk for feeding one's own child without processing by a SoHO entity.

In addition to improving safety and quality, the regulation aims to increase harmonisation across the EU and to facilitate cross-border exchanges and access to SoHO. There will be an intense programme of work, led by the European Commission, to ensure that all member states are ready and fully operational for the implementation date in 2027.To elaborate slightly, that programme of work will include the establishment of an EU-level SoHO coordination board that will support member states in the implementation of the regulation. Northern Ireland will continue to have access to information through EU-UK structures set up as a result of the Windsor framework.

The programme will also include the introduction of common, EU-wide procedures for the authorisation and assessment of SoHO preparations. Member states will designate a SoHO national authority and other competent authorities to authorise SoHO preparations and ensure the independent and transparent oversight of related activities. The programme includes additional authorisation and inspection requirements for establishments that process, store, release, import or export SoHO, and it covers the establishment of a new common IT platform — the EU SoHO platform — to register and exchange information on related activities. Designated SoHO-competent authorities should be independent from any SoHO entity. Some competent authorities will need to carry out new activities. Further work is ongoing with the UK regulators and the Department of Health and Social Care to ensure that regulators are operationally prepared for the implementation date.

The regulation requires SoHO entities to:

> *"ensure respect for the dignity and integrity of SoHO donors."*

It also requires them to:

> *"ensure high levels of safety and protect the health of living SoHO donors from risks related to the SoHO donation, by identifying and minimising such risks before, during and after the SoHO collection."*

That means that SoHO entities must protect the health of recipients and the offspring of medically assisted reproduction from any risks posed by SoHO and their human application within the scope of their respective competences.

The regulation requires member states to collaborate with SoHO national authorities, SoHO competent authorities and SoHO entities in order to:

"consider all reasonable efforts for achieving a sufficient, adequate and resilient supply of critical SoHO with a view to appropriately meet recipients' needs, and to contribute to European self-sufficiency."

The regulation obligates the European Commission to:

"establish, manage and maintain a digital platform to facilitate efficient and effective exchange of information concerning SoHO activities in the Union".

Although most of the policy areas noted in the legislation are devolved, reproductive tissues and cells policy is a reserved matter. Intestinal microbiota and blood preparations that are not used for transfusion are transferred to Northern Ireland and are reserved for Wales and Scotland.

I turn to the UK Government's position. As we noted in the assessment template that the Committee has received, the extent of any impact of the SoHO regulation in Northern Ireland will depend on the position that the UK Government adopt relative to the new standards and on whether that will affect the movement of SoHO between GB and Northern Ireland. The Department of Health and Social Care in England has been actively leading on that, and its officials have engaged with the European Commission and engaged extensively with the relevant competent authorities at national level. DHSC officials have also engaged with us and the other devolved Administrations, so their input has been provided in the assessment template. I will draw out some of the key points to assist the Committee in its consideration.

First, the movement of SoHO from GB to Northern Ireland facilitates their use in life-changing and life-saving treatments. The UK Government's assessment is that tissues and cells are the most commonly moved substances between GB and Northern Ireland and we currently have equivalent standards in those areas. The UK Government continue to engage with the European Commission on any updates to those standards and requirements and will keep them under close review. Given the importance of SoHO, the UK Government will take action, as needed, to ensure GB-originating SoHO can be supplied to Northern Ireland.

Secondly, the template states:

"The UK is a leader in transfusion, transplantation, pharmaceuticals and food safety. The changes in the Regulation that apply in NI will not come at the expense of public health, patient safety, and access, as the Regulation allows more stringent protective measures to be implemented."

The UK Government state that they:

"do not anticipate that changes to the safety and quality standards set out in this Regulation will significantly impact the movement of SoHO from GB to NI."

Thirdly, they state:

"In line with the Government's commitment to ensuring NI businesses have unfettered access to the rest of the UK internal market, the measures set out in the SoHO Regulation will in no way impede the movement of qualifying Northern Ireland goods from Northern Ireland to Great Britain."

Fourthly, the scope of substances covered by the regulation has been increased compared with the existing blood, tissue and cells (BTC) directives. The UK Government state that they:

"will engage closely with the EU, regulators, and affected stakeholders on changes to standards and requirements that apply."

We can draw some assurance from that, and we will remain in close contact with the Department of Health and Social Care. It is important to note, however, the programme of work that I referred to, which is under way between now and 2027.

The template contains a lot more information on the existing UK common frameworks and on the substances and their clinical application in Northern Ireland, but, in the interest of time, I will pause and allow for questions from members.

The Chairperson (Mr McGuigan): Thank you. We received the updated EM just this morning, and it is extensive. Let me put it this way: there is a lot of detail in it. When you went through your evidence, you said that access was key and that a lot would depend on what the British Government did. In the new EM, the UK Government say:

> *"while the Regulation creates some new operational requirements for entities carrying out SoHO activities"*

— in the North —

> *"and for competent authorities, this is unlikely to prevent the movement".*

They are saying that it is unlikely that there will be impact on movement. A lot of the other stuff that is devolved is subject to common frameworks. You said that there will be no negative impacts on public health here. Also, in some parts of the regulation, the British Government have the ability to bring about a derogation. Considering that in terms of the Committee's role and remit, the impact seems to be positive rather than negative. Is that the case? Can you say whether this legislation would have any negative impact on the population here?

Mr Wilson: In my evidence, I was quoting the input that we received from the Department of Health and Social Care, so it reflects the UK Government's position. We received the revised explanatory memorandum this morning and have not yet had time to go through it in great detail. You will be aware that an EM was published in 2022. There have been some updates to that, but our understanding of the substance of it is that there has been no significant movement from the position in 2022. Assurances have been provided on the potential impacts on public health or on the movement of substances.

Our Department's position on the assessment template that was provided to the Committee is that the impact is not known. We can say that the regulation that has been introduced by the EU is a positive development that builds on the existing high safety and quality standards, and that is to be welcomed. The impact will be determined by whether any divergence emerges, and, on the basis of our engagement with the UK Government, it seems that there is a commitment to ensuring that that does not happen.

The Chairperson (Mr McGuigan): We have a time frame of four to six weeks. Will we know within that time the information that you currently do not know?

Mr Wilson: It is doubtful that the position will change, because of the extent of the programme of work that needs to take place over the next number of years. Brenda may want to add to that.

Ms Brenda McGilligan (Department of Health): That will be reliant on the SoHO coordination board being set up in the EC. When that board is established, the programme of work on the finer technical detail will be taken forward. From what we understand, that may not commence until early 2025. It is hoped, however, that the SoHO coordination board will be set up in the autumn of this year.

The Chairperson (Mr McGuigan): So the Committee will not receive any information on top of what you have given us and the EM in the next period of time.

Mr Wilson: No, it is doubtful.

The Chairperson (Mr McGuigan): OK. Thank you.

Mr Brooks: What discussions have there been on the common frameworks? You said that what the EU is doing is positive: is there any sense that the rest of the UK will voluntarily align in that regard?

Mr Wilson: That has been the tone of our discussions with Department of Health and Social Care colleagues. It makes sense that they would want to do that because the substances move between European nations and the whole of the UK.

Ms McGilligan: It is also our understanding that the next common frameworks meeting will be in September or October.

Mr Brooks: Thank you very much. Of the SoHO that move back and forth from GB, how much is public or NHS-related and how much is from private actors and laboratories and so on? What is the breakdown of that?

Mr Wilson: We have no detailed data on that. Our focus and the briefing that we have provided is on movement within public health systems: the NHS and Health and Social Care (HSC). There is dependency in most of the areas covered by the SoHO regulation. You could say that Northern Ireland is relatively self-sufficient in some of those areas, such as bone products and breast milk, which is an all-island service. Our understanding is that there is not much, or any, movement of those substances in an east-west direction. That aligns with the advice that the UK Government have provided that most of the movement is in relation to blood, tissues and cells. Patients in our public health system use those substances.

Mr Brooks: On the inspection and oversight of all of this, is an increased EU footprint envisaged here? How would that be carried out?

Ms McGilligan: Again, we will not know that until the technical detail has been taken forward.

Mr Brooks: OK. Thank you.

Dr Aiken: You have also just seen the revised EM, so we are all in the same situation. Your situation still is that you cannot make a recommendation because you do not know yet: the information is not there on either of the questions, so that has not fundamentally changed. We do not know what the relationship will be between the European Directorate for the Quality of Medicines and HealthCare (EDQM) and the European Centre for Disease Prevention and Control (ECDC) or the impact that that will have. I go back specifically to the COVID period. The then Health Minister had real concerns about access to stuff coming from GB into Northern Ireland and how to maintain those supply and flow lines. You are not yet in a position to say what the implications of the SoHO regulation on the overall supply lines would be, because you have not had a chance to look at the detail. I do not want to put words into your mouth: is that correct?

Ms McGilligan: Yes.

Dr Aiken: The situation at the moment is that we do not know.

Ms McGilligan: Yes.

Dr Aiken: OK. That is clear. Thank you very much.

Ms Egan: Thank you for coming in today. My question is about human breast milk, particularly the all-island service, which, I understand, is run from the Western Health and Social Care Trust. If there was significant divergence, how would it affect premature babies who access that all-island service?

Mr Wilson: Our current understanding is that there would be no impact there. The divergence would be in the UK's position relative to Europe. The human breast milk service is an all-island service, so donors and recipients are from across both jurisdictions on the island. Our current understanding is that a change in quality standards would have no impact because there is no movement of that substance from GB into Ireland. Do you have anything to add, Brenda?

Ms McGilligan: My understanding is that we are self-sufficient in human breast milk through the all-Ireland approach.

The Chairperson (Mr McGuigan): Grand job. Thank you very much.

Ms McGilligan: Thank you.

Mr Wilson: Thank you.